UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF WASHINGTON

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| ZACHARY PILZ, an individual, BRENDA CONTINE, an individual, JUAN LOPEZ, an individual,<br><br>*et al.*<br><br>Plaintiffs,<br><br>v.<br><br>JAY INSLEE, the Governor of the State of Washington,<br><br>*et al.*<br><br>Defendants. | CASE NO. 3:21-cv-05735-BHS<br><br>DECLARATION OF DR. ROBERT MALONE, MD, MS<br><br>JURY DEMANDED |

Dr. Robert Malone declares under penalty of perjury.

1. I am an adult citizen of the State of Virginia, County of Madison, am competent to testify, and hereby make this declaration of my personal knowledge.

2. I graduated from the University of California, Davis with a Bachelor of Science degree in Biochemistry in 1984.



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3. I graduated from Northwestern University Medical School, Feinburg School of Medicine, in 1991.
4. I received one year of pathology residence training at University of California, Davis Sacramento Medical Center.
5. I completed a Masters' Degree in Biology from University of California, San Diego in 1989 for work performed primarily at the Salk Institute in the Molecular Biology and Virology :Laboratories and Laboratory of Dr. Inder Verma. This and subsequent work at the San Diego corporation "Vical" resulted in nine issued domestic US patents describing mRNA and DNA vaccine platform technology.
6. I completed a Giannini post-doctoral research fellowship at University of California, Davis Department of Pathology in 1992.
7. I completed a Harvard Medical School Global Clinical Research Scholars fellowship in 2016. This fellowship included an emphasis on regulatory affairs, clinical development, bioethics, epidemiology and biostatistics.
8. I am currently licensed to practice medicine in the State of Maryland
9. I have been extensively and repeatedly trained in clinical research bioethics over many years at a variety of institutions including intensive training by Dr. Adil Shamoo of the University of Maryland, Baltimore.
10. I have served as Assistant and Associate Professor of Surgery and/or Pathology at University of California, Davis School of Medicine, University of Maryland School of Medicine, and the Uniformed University of the Health Sciences between 1992 and 2001. During this period, I was awarded numerous peer-reviewed and industrial grants and contracts relating to gene delivery technology, genetic vaccine development, the chemistry



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and formulation of gene delivery reagents such as those used for mRNA vaccines, mucosal genetic vaccine development and other related topics. This work resulted in numerous additional granted US Patents in these fields and the incorporation of biotechnology companies based on these discoveries including Inovio vaccines.

11. I have served as Associate Director, Clinical Research at Dynport Vaccine Company LLC from 2002-2003, supporting the prime systems US DoD contract for all biodefense products under advanced development by the Department of Defense.

12. I have served as Director, Business Development and Program Management for the Bill and Melinda Gates funded Aeras Global TB Vaccine Foundation from 2004-2005.

13. I have served as Senior Medical Director, Summit Drug Development Services (a Regulatory Affairs and Clinical Research specialty contract research organization) from 2005-2006

14. I have served as Director, Clinical Development & Medical Affairs, Influenza for Solvay Pharmaceuticals (currently Abbvie) from 2006-2008

15. I have served as Medical Director, Vaccines for the Beardsworth Consulting Group from 2010 – 2013

16. I currently serve as CEO and Principal Consultant for RW Malone MD LLC, primarily supporting the US Department of Defense, Defense Threat Reduction Agency (via contracts held by Leidos and MIT-Lincoln Lab). I have been leading or serving as a principal consultant for teams developing both repurposed drugs or vaccines since January 04, 2020, resulting in multiple novel findings, published and pending manuscripts, three clinical trials involving repurposed drugs (two in USA under DoD funding, one in India under funding from Reliance Healthcare) and one Phase 1 clinical trial for a novel SARS-CoV-2 vaccine.



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17. I have a history of over a decade of service to the NIAID as either reviewer or study section chairperson for evaluating large contract bids for development of Biodefense and other Medical Countermeasures against emerging infectious diseases and biothreat agents.

18. I currently sit on the NIH/FNIH ACTIV COVID-19 Drug development panel.

19. I have served as co-author of a book entitled "NOVEL CORONAVIRUS: A Practical Guide for Preparation and Protection (originally published Feb 2020).

20. I have played a key role in the discovery and clinical development of the repurposed drugs Famotidine and Famotidine + Celecoxib as treatment for both outpatient and inpatient COVID-19 disease, and have academic publications relating to this work. This work has yielded FDA and Indian health authority approved INDs for clinically testing these agents in outpatient and inpatient randomized controlled trials.

21. I have supported the Indian corporation Reliance in development of a second generation SARS-CoV-2 vaccine that is now IND approved by the Indian health authority for initiation of clinical trials which are anticipated for Q4 2021.

22. I have previously served as an expert witness in cases relating to vaccine development, COVID-19 and related topics.

23. Together with Dr. Peter Navarro, I have developed and published (lay press, Washington times) public policy recommendations involving targeting SARS-CoV-2 vaccine deployment to high risk groups (elderly, morbidly obese, immunodeficient and others), providing early COVID-19 treatment options (including antibody therapies), home diagnostic tests, and computational algorithms enabling individual assessment of COVID-19 risks.

24. Attached as Exhibit A is a true and correct copy of my curriculum vitae.



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25. I have reviewed the arguments for vaccine mandates made by Dr. Lindquist summarized in
26. NO. 21-2-00411-36 DECLARATION OF DR. SCOTT W. LINDQUIST
27. NO. 21-2-01674-34 SECOND SUPPLEMETNAL DECLARATION OF DR. SCOTT W. LINDQUIST
28. I concur with Dr. Lundquist that SARS-CoV-2 infection and COVID-19 disease (which develops in a subset of infected individuals) represent a significant threat to the life, health and well-being of elderly (typically over 65 years of age), the morbidly obese in all age groups, and those with high risk conditions in all age groups, and concur that it is highly appropriate to make the current experimental vaccines widely available to individuals within those risk categories who elect to accept those vaccines after the following conditions have been met:
29. A) That a full and complete disclosure of the risks of vaccine acceptance has been made,
30. B) That those risks have been disclosed in a manner that results in full comprehension of those risks,
31. C) That those individuals accepting vaccine do so of their own free will, without either coercion or enticement.
32. These specific criteria are enumerated as key statutory components of the Code of Federal Regulations 45 CFR 46 (subpart A), referred to as "The Federal Policy for the Protection of Human Subjects" (also known as the "Common Rule").
33. These criteria are most clearly enumerated in the US Federal Government's "Belmont Report", which provides the basis for 45 CFR 46 (subpart A), and is available at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html .



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34. Regarding informed consent and experimental medicines, the Belmont report clearly describes informed consent as "Informed Consent. — Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied."

35. The Belmont Report further states that "While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness."

36. In my opinion, these three elements are not being met in the case of Proclamation 21-14 as issued by Governor Inslee, which prohibits anyone from working for any state agency after October 18, 2021 if the worker has not been fully vaccinated against the vaccine. Proclamation 21-14 also prohibits any health care provider or an individual or entity that operates a health care setting from failing to be fully vaccinated against COVID-19 after October 18, 2021.

37. Specifically,

38. 1) The residents of the State of Washington only have access to unlicensed vaccine products available to them under the emergency use authorization declarations correctly cited by Dr. Lundquist in his sworn testimony. Therefore Proclamation 21-14 is mandating administration to experimental medical products to those who work for any state agency after October 18, 2021 or any health care provider or an individual or entity that operates a health care setting.



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39. 2) Those at risk for mandated vaccination and potential vaccine-induced injury do not have access to full disclosure of vaccine-associated risks as understanding of the spectrum and breadth of those risks continues to evolve. This is clearly documented in the FDA in BL 125742/0 : Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products (available at https://www.fda.gov/media/151710/download ). This FDA document states "We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis. Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks." With this statement, the FDA has clearly acknowledged that the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is inadequate to identify serious risks associated with any SARS-CoV-2 vaccines. Therefore, by clear and explicit admission of the US FDA, the information required to insure that serious risks of vaccination with any SARS-CoV-2 vaccines available in the USA, whether under FDA EUA or marketing authorization, is not sufficiently characterized to enable full disclosure of those risks to the citizens, employees, or health care personnel of the State of Washington, and the requirement for full disclosure of risks included in 45 CFR 46 (subpart A) cannot and is not being met.

40. The deficiencies of the current US Government system for tracking critical pandemic information including adverse events associated with these or other vaccines are partially



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described in a recent Washington Post article available at https://www.washingtonpost.com/health/2021/09/30/inadequate-us-data-pandemic-response/

41. 3) To the best of my knowledge, Proclamation 21-14 has made no provision mandating that the risks known to be associated with the SARS-CoV-2 vaccines be communicated in a methodical, structured, and easily understood fashion as required for any clinical trial or medical procedure otherwise conducted in the State of Washington. I am unaware of any program or effort by the State of Washington to fulfill this requirement of 45 CFR 46 (subpart A) in the context of fulfilling the provisions and mandate of Proclamation 21-14.

42. 4) To the best of my knowledge, Proclamation 21-14 includes no clause directing that those who are directed to receive SARS-CoV-2 vaccines provide signed verification that they are receiving these experimental medical products of their own free will, without either coercion or enticement, as required for any clinical trial or medical procedure otherwise conducted in the State of Washington. I am unaware of any program or effort by the State of Washington to fulfill this requirement of 45 CFR 46 (subpart A) in the context of fulfilling the provisions and mandate of Proclamation 21-14. The wording of Proclamation 21-14 appears to meet the specific characteristics and criteria of coercion of acceptance of experimental medical products.

43. Dr. Lundquist, while well trained, qualified and experienced in the areas of medicine, Infectious Disease, and public health, appears to lack knowledge, training and experience in Regulatory Affairs and the associated federal code as interpreted by the FDA, and is therefore not qualified to provide expert opinion on the issue of whether the experimental medical product referred to by the FDA as the "Pfizer-BioNTech COVID-19 Vaccine for



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the prevention of COVID-19" (herein after referred to as "Pfizer vaccine", see for example https://www.fda.gov/media/150386/download ), and the medical product referred to by the FDA by the brand name COMIRNATY, under marketing authorization to BioNTech Manufacturing GmbH (herein after referred to as "COMIRNATY", see for example https://www.fda.gov/media/151710/download ) represent the same or different products.

44. Dr. Lundquist appears to argue in his sworn deposition that these two legally distinct products are interchangeable due to the FDA assertion that the formulation and constituents of these two legally distinct product are substantially identical. This testimony appears to be based on incorrect understanding that a regulated product authorized for marketing by the FDA consists only of the active drug substance as delivered into a vial or other container in the case of an injectable vaccine.

45. In the case of either the Pfizer vaccine or COMIRNATY, the legally distinct products described by the FDA documents available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine , these and any other FDA regulated medicinal product consists of the entirety of the data supporting the safe and effective use of the product, as well as the quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment, and packaging & labeling of the product (see for example https://www.fda.gov/media/92847/download ). Packaging and labeling specifically includes package insert summarizing the data supporting the intended safe and effective use, and also describing the risks associated with the medical product.



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46. As is clearly stated in the aforementioned FDA documents describing the Pfizer vaccine or COMIRNATY, these packaging and labeling aspects which are intrinsic aspects of the regulated product are explicitly not identical between these two legally distinct products.

47. Therefore, the Pfizer vaccine and COMIRNATY are neither identical legally nor functionally. In at least one key aspect, COMIRNATY includes FDA approved labeling and a package insert designed to inform the recipient of the (incomplete, as recognized by the FDA) list of risks and benefits of the product, whereas the Pfizer vaccine does not.

48. There may be other differences between the Pfizer vaccine and COMIRNATY in the totality of the products in terms of quality systems, production methods and processes, laboratory assays (including in-process and release assays), materials, facilities & equipment. The provided FDA communication appears to assert that the materials used and final formulation is essentially identical, but potential differences in addition to the differences in packaging and labeling are not explicitly addressed.

49. On the basis of these facts and observations, it is my expert opinion that the Pfizer vaccine and COMIRNATY are not identical, and that the FDA has appropriately identified them as legally separate and distinct products.

50. It is my expert opinion that assertions and inferences by Dr. Lundquist that the Pfizer vaccine and COMIRNATY are identical is not based in regulatory or legal fact, and that the FDA clearly states that they are legally separate products.

51. It is my expert opinion, based on the aforementioned FDA communications available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine and the FDA EUA communication documents previously cited by Dr. Lundquist, that the FDA regulated



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product labeled COMIRNATY is the only licensed SARS-CoV-2 vaccine available to the citizens, employees, and health care workers of the State of Washington.

52. To the best of my understanding, the FDA regulated product labeled COMIRNATY is still being manufactured, filled, finished, labeled and packaged, and is not yet available to the citizens, employees, and health care workers of the State of Washington.

53. Based on this understanding, it is my expert opinion that all SARS-CoV-2 vaccines currently available to the citizens, employees, and health care workers of the State of Washington are not authorized for marketing by the FDA; all available doses currently available are experimental medical products made available as such by the FDA and US HHS under the Emergency Use Statutes and Authorizations (EUA) as previously cited by Dr. Lundquist.

54. In my expert opinion, as all vaccine products available to the citizens, employees, and health care workers of the State of Washington are experimental products made available under FDA EUA, the administration of such products fall under the "common rule" (45 CFR 46 (subpart A)) which enumerates in federal law the fundamental bioethical principals which guide clinical research, and represent current US federal legislative and legal interpretation of the Nuremburg code, The Geneva Convention, the Helsinki declaration, the Belmont Report and the entire structure which supports ethical human subjects research in the United States, and which requires that research subjects be fully informed of risks and must freely consent to participation in such research without coercion or enticement.

55. I agree with Dr. Lundquist that the experimental vaccines available under FDA EUA in the United States meet commonly accepted criteria for effectiveness in prevention of disease and death at this time, based on the data currently available for the circulating strain of



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SARS-CoV-2 associated with the original infections such as those previously diagnosed by Dr. Lundquist. However, as Dr. Lundquist correctly notes in his testimony, these strains are being rapidly displaced by circulating viral genetic variants including the subtype commonly referred to as "Delta", which are considerably more resistant to protective vaccine effects for prevention of viral infection, replication, and transmission.

56. It is my expert opinion that the current vaccines available under FDA EUA were based on the viral sequences and amino acid sequence and composition of the SARS-CoV-2 Spike protein as described in early viral isolates (largely from China) which are substantially similar to the historic virus associated with the viral strain infecting the patients originally diagnosed by Dr. Lundquist. However, these vaccine sequences and compositions are not identical to the SARS-CoV-2 Spike protein associated with Delta and other virus isolates currently circulating the United States. Therefore, by definition, the current vaccines available under FDA EUA are mismatched to currently circulating viruses.

57. Dr. Lundquist provides testimony concerning the reproductive coefficients of the historic viral strains previously circulating in the State of Washington. These estimates appear to be outdated and misleading. The US CDC has provided information concerning the reproductive coefficient values associated with the currently circulating Delta strain of SARS-CoV-2. These baseline reproductive coefficients ($R_o$) provided by the US CDC are estimated as varying between 5 and 8 (see CDC slide #15 at https://context-cdn.washingtonpost.com/notes/prod/default/documents/54f57708-a529-4a33-9a44-b66d719070d9/note/7335c3ab-06ee-4121-aaff-a11904e68462.#page=1 ).

58. The CDC has analyzed the epidemiologic consequences and interactions between current CDC estimates of vaccine efficacy for prevention of infection (as opposed to prevention of



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disease, which Dr. Lundquist has misleadingly focused on) and the high reproductive coefficient associated with the Delta strain, and has concluded that these vaccines are not sufficiently effective in preventing infection by Delta to be able to stop the spread of the virus even in the event of 100% vaccine acceptance (see slides 20, 21 in https://context-cdn.washingtonpost.com/notes/prod/default/documents/54f57708-a529-4a33-9a44-b66d719070d9/note/7335c3ab-06ee-4121-aaff-a11904e68462.#page=1 ).

59. The CDC has concluded that breakthrough infections in those previously vaccinated with the mismatched vaccines currently available in the USA under FDA EUA may be as transmissible to third parties (vaccinated or unvaccinated) as infections occurring in unvaccinated persons (see slide 17 in https://context-cdn.washingtonpost.com/notes/prod/default/documents/54f57708-a529-4a33-9a44-b66d719070d9/note/7335c3ab-06ee-4121-aaff-a11904e68462.#page=1 . The technical vaccinology term describing this phenomenon of breakthrough infection in previously fully vaccinated individuals is "leakiness". As documented by the CDC and many peer reviewed academic publications, the current experimental vaccines available to the citizens, employees, or health care personnel of the State of Washington are considerably "leaky", and unable to provide and insure adequate workplace protection against infection and spread of currently circulating strains of SARS-CoV-2 to the citizens, employees, or health care personnel of the State of Washington- even if there is full (100%) compliance with the terms of the mandate described in Proclamation 21-14.

60. Based on these and other findings and scientific reports, it is my expert opinion that, while vaccination with the experimental vaccines available to Washington State citizens may



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provide statistically significant improvements in the risk of severe disease or death to the citizens, employees, or health care personnel of the State of Washington that become infected with SARS-CoV-2, they do not and cannot provide adequate protection against infection, replication and spread of SARS-CoV-2 to the citizens, employees, or health care personnel of the State of Washington, and therefore are unable to meet the objectives of the vaccine mandate described in Proclamation 21-14.

61. In sum, it is my expert opinion that;

62. 1) There are no FDA licensed SARS-CoV-2 currently available for purchase or use in the United States.

63. 2) All SARS-CoV-2 vaccines currently available to the citizens, employees, or health care personnel of the State of Washington are experimental medical products.

64. 3) The experimental SARS-CoV-2 vaccines currently available to the citizens, employees, or health care personnel of the State of Washington are mismatched to the currently circulating vaccine- resistant viral strains including "Delta", and are not sufficiently effective in preventing infection, replication, and transmission of currently circulating SARS-CoV-2 viral variants to meet the objectives of Proclamation 21-14.

65. 4) The vaccine mandate described in Proclamation 21-14 is in violation of well accepted western bioethical norms for informed consent as stipulated in 45 CFR 46 (subpart A) otherwise known as the "common rule", and which governs the administration of experimental medical products in the United States.

66. 5) Irrespective of the intent or purpose of Proclamation 21-14, there are no SARS-CoV-2 vaccines, whether licensed or unlicensed, which are sufficiently effective in preventing infection, replication, and transmission of currently circulating SARS-CoV-2 viral variants



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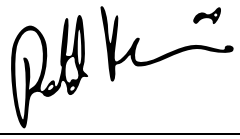
to meet the objectives of Proclamation 21-14 as a public health directive designed to insure protection of the citizens, employees, or health care personnel of the State of Washington from infection, replication, and spread of currently or likely future circulating strains of vaccine-resistant SARS-CoV-2 virus.

EXECUTED this 13th day of October 2021 at Madison, VA



Dr. Robert W Malone, MD, MS

Exhibit A

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## *PROFESSIONAL EXPERIENCE*

Dr. Malone is a specialist in clinical research, medical affairs, regulatory affairs, project management, proposal management (large grants and contracts), vaccines and biodefense. This includes writing, developing, reviewing and managing vaccine, bio-threat and biologics clinical trials and clinical development strategies. He has been involved in developing, designing, and providing oversight of approximately forty phase 1 clinical trials and twenty phase 2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on approximately forty phase 1 clinical trials, and on twenty phase 2 clinical trials, including those run at vaccine-focused Clinical Research Organizations. He has served as principal investigator on some of these. Examples of his infectious disease pathogen advanced (clinical phase) development oversight experience include HIV, Influenza (seasonal and pandemic), Plague, Anthrax, VEE/EEE/WEE, Tularemia, Tuberculosis, Ebola, Zika, Ricin toxin, Botulinum toxin, and Engineered pathogens. In many cases, this experience has included vaccine product development, manufacturing, regulatory compliance, and testing (manufacturing release and clinical) aspects. In most cases, his oversight responsibilities have included clinical trial design, regulatory and ethical compliance, and laboratory assay strategy, design, testing and performance.

Dr. Malone has a history of assembling and managing expert teams that focus on solving complicated biodefense challenges to meet US Government requirements. He was instrumental in enabling the PHAC/rVSV ZEBOV ("Merck Ebola") vaccine to move forward quickly towards BLA



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and (now recently granted) licensure. Dr. Malone got the project on track in support of DoD/DTRA and NewLink Genetics, recruited organizations to team with USAMRIID/WRAIR to develop the immunoassays, put WHO and Norwegian government philanthropic leadership in touch with Pentagon leadership to expedite the initial WRAIR clinical and ring vaccination trials, recruited a management team, recruited Merck vaccines to purchase the product candidate from NewLink, helped write and edit the clinical trials developed by the World Health Organization and lead the development of the BARDA and DTRA contracts - yielding over 200M$ in resources. Dr. Malone's early involvement in this project allowed for the Merck vaccine to be developed very rapidly.

Currently, Dr. Malone is leading a large team since January 10, 2020, focused on clinical research design, drug development, computer modeling and mechanisms of action for COVID-19 treatment. This work has included multiple manuscripts summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease, and others focused on Celecoxib and Famotidine are being reviewed for publication. He has developed and wrote the initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults. Another project he has been involved with is a DTRA/DOMANE-funded development and performance of a virtual outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example. He has helped open an IND for famotidine use for treatment and prevention of COVID19 disease including an associated drug master file, and has enabled teaming/pharmaceutical supply arrangements with two major pharmaceutical firms.

Dr. Malone has extensive research and development experience (bench to bedside) in the areas of pre-clinical discovery research, clinical trials, vaccines, gene therapy, bio-defense, repurposing drugs for infectious diseases, high throughput screening and immunology. He has over twenty years of management and leadership experience in academia, pharmaceutical and biotechnology industries, as well as in governmental and non-governmental organizations. He often serves as study section chairperson for NIAID contract study sections relating to biodefense medical product development. He is currently a topic editor for the journal Frontiers in Pharmacology, in the area of "Treating COVID-19 With Currently Available Drugs."

Scientifically trained at UC Davis, UC San Diego, and at the Salk Institute Molecular Biology and Virology laboratories, Dr. Malone is an internationally recognized scientist (virology, immunology, molecular biology) and is the original inventor of mRNA Vaccination, DNA Vaccination, and multiple non-viral DNA and RNA/mRNA delivery technologies. Dr. Malone holds numerous fundamental domestic and foreign patents in the fields of gene delivery, delivery formulations, and vaccines: including DNA and RNA/mRNA vaccines.

Dr. Malone received his medical training at Northwestern University (MD) and Harvard University (Clinical Research Post Graduate) medical schools, and in Pathology at UC Davis. Dr. Malone is currently finishing up his board certification in medical affairs (BCMAS).



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Dr. Malone has approximately 100 peer-reviewed publications and published abstracts and has about 12,000 citations of his peer reviewed publications, as verified by Google Scholar. His google scholar ranking is "outstanding" for impact factors. He has been an invited speaker at over 50 conferences, has chaired numerous conferences and he has sat on or served as chairperson on numerous NIAID and DoD study sections.

***SUMMARY OF ACCOMPLISHMENTS / SKILLS***

- A senior executive and scientist with a highly successful track record of leading bench and discovery research through FDA Phase I, II, and III clinical trials, protocol development and submission, and related regulatory submissions including pIND and IND.
- Significant expertise in drug development and delivery.
- Specialist in Medical Affairs.
- Special in Regulatory Affairs.
- Domestically trained, Maryland Licensed Physician/Scientist.
- Experienced capturing and managing large federal contracts (including BARDA) with over 9 billion in ID/IQ awards and almost a billion USD in government contracts won and/or managed in the last decade.
- Expertise in pathology, infectious disease, pandemic clinical trials, influenza, regulatory affairs, project management, biodefense, HIV and Ebola. A verified list of capture is available upon request.
- Significant expertise with federal contracting, grants, international NGO health related research and development coupled with professional relationships at CDC, DoD, HHS (BARDA, CDC, FDA and NIAID).
- Prior and current service on many federal study sections and oversight boards involving infectious disease, vaccine, and biodefense.
- Experienced and formally trained as a Business Development Professional, project manager, capture/proposal manager, color team reviewer and editor for projects valued from 10M$ up to 1B$ US, with experience managing processes and teams in a wide variety of non-profit and for-profit corporate cultures including both matrix and traditional environments.
- Highly skilled in fostering a culture of innovative problem solving within project teams.
- DoD Secret Clearance authorized.
- Expert witness experience, with extensive training from some of the top attorneys/law firms in the USA.
- Graduated from the Harvard Medical School Global Clinical Scholars Research Training Program with distinction, a year-long program focused on international clinical research. This program combines on-site (London & Boston) as well as distance learning, with an average of 15h per week lecture and practicum exercises.
- Dr. Malone will be board certified in medical affairs (BCMAS) by April, 2021. The BCMAS program is the certification program developed by the Accreditation Council for Medical Affairs (ACMA).
- Inventor of mRNA and DNA vaccination platform technologies.



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**RW Malone MD, LLC**
***CEO and Principal Consultant:*** 2001-Present

Dr. Malone has been involved in developing, designing, and providing oversight of approximately forty phase-1 clinical trials and twenty phase-2 clinical trials, as well as five phase 3 clinical trials. He has served as medical director/medical monitor on approximately forty phase-1 clinical trials, and on twenty phase-2 clinical trials, including those run at vaccine-focused Clinical Research Organizations. He has served as principal investigator on some of these. Providing business development, proposal management, clinical trials development, expert witness, regulatory and medical affairs support for pharmaceutical, vaccines-related and biologics companies as well as related regulatory submissions including pIND and IND.

**Projects include**:

- Led a large team since January 10, 2020, focused on drug development, computer modeling and mechanisms of action for COVID-19 and is now preparing a manuscript summarizing most recent findings relating to famotidine and overall insights into the mechanism of COVID-19 disease.
- Clinical trials protocol development: Developed and wrote initial clinical trial design: A Single Center, Randomized, Double Blinded Controlled Crossover Observational Outpatient Trial of the Safety and Efficacy of Oral Famotidine for the Treatment of COVID-19 in Non-Hospitalized Symptomatic Adults.
- Proposed is a DOMANE/WRAIR joint development and performance of outpatient clinical trial designed to test new monitoring and data capture technology while using COVID19 as a live-fire example.
- Opening IND for famotidine use for treatment and prevention of COVID19 disease with associated drug master file.
- Principal Regulatory Consultant, Clinical Network Services (CNS)/Novotech, 2018-2019. Regulatory, clinical and business development support.
- Served as an expert witness with specialized training, 2017 - present.
- Ebola vaccine project for NewLink/Bioprotection Systems (rVSVdG ZEBOV Ebola vaccine project), resulting in well over 100M USD non-dilutive capital to NL/BPS. This also included working with the World Health Organization as well as initial set up of the licensing deal to Merck Vaccines of the Ebola vaccine.
- Served as Medical Director, Beardsworth, half time position on retainer, 2010 – 2013.
- Service on federal biotechnology/vaccines proposal study sections (multiple).
- Served as Editor-In-Chief of Journal of Immune Based Therapies and Vaccines 2007-2012
- Service on Safety Monitoring Committee, Phase 1 safety/immunogenicity of novel Influenza vaccine
- Consulting support for multiple vaccine-focused clinical sites in US and Latin America.
- Served as Medical Director, Vaccines with Accelovance, Inc. (2008 – 2009).
- Served as medical monitor for multiple seasonal and pandemic (H1N1) studies.
- Review and edit clinical protocols.



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- Examples of multi-year contract clients include Accelovance, Alchem Laboratories, Avancer, Beardsworth, Chesapeake Perl, Corium, DOAR, ITS, ITT-Exelis, EpiVax, Jean Brown Research, Opgen, Quest Diagnostics (Focus), PaxVax, SAI, Soligenix, TASC, Univ of MA.
- Commercial intelligence work for two of the largest pharmaceutical companies in the world (sub-contractor).
- Partnering with Galloway and Associates (Darrell Galloway) 2012-2014.
- Acting as *Managing Director, Clinical Development and Government Affairs* for the Avancer Group. April 2012 – 2016.
- Proposal development (patch-based vaccine delivery, Tularemia vaccine, CDC contract for clinical trials site development, international government and NGO contract and grant solicitations) – Aeras Global TB Vaccine Foundation 2003-2005.
- Proposal development (plague vaccine- HHS), Technical diligence – VaxGen Corporation.
- Consulting services for EpiVax, 2005-2018 (member, Scientific Advisory Board), 2020.
- Consulting services for Aldevron, LLC.
  2001-2005 (operating as Gene Delivery Alliance).
- Business and proposal development in the areas of Bioinformatics and Life Sciences (including telemedicine) and research at the University of Bern, Switzerland.
- Consulting services for Molecular Histology, Inc. with the title of Medical Director.
- Collaboration with Inovio, including incorporation of company in the USA.
- Consulting services for MSD, Inc. for business/ technology development planning.

**Alchem Laboratories**
***Chief Medical Officer***

This position was as a consultant, but then full time FTE. Consulting for Alchem and/or its CEO: 2012 –2019. CMO 11/2019 to 4/2020.

- Led a high through-put screening and research team for drug development 2019-2020.
- Dr. Malone began modeling and focusing on the Plpro (papain-like protease) and Mpro (main protease) of then novel coronavirus (now SARS-CoV-2) using computational tools including Modeller to generate homology-modeled crystal structures for the SARS-CoV-2 Plpro and Mpro. Which generated a candidate list for COVID-19, which was reduced to a few candidates, based on binding sites, safety, licensure, efficacy, bioavailability of drug candidates.
- Lead the discovery and development of famotidine for the Treatment of COVID-19.
- Technical Lead/writer for funded full proposal under BAA-18-100-SOL-00003 Amendment 15 entitled: "A Multi-site, Randomized, Double-Blind, Multi-Arm Historical Control, Comparative Trial of the Safety and Efficacy of Hydroxychloroquine, and the Combination of Hydroxychloroquine and Famotidine for the Treatment of COVID-19 in Hospitalized Adults."
- Developed and wrote initial clinical trial design for a comparative trial of the safety and efficacy of hydroxychloroquine, and the combination of hydroxychloroquine and famotidine for the treatment of COVID-19 in hospitalized adults.

**Atheric Pharmaceutical, LLC**



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*CEO, and Co-founder.*
Feb 2016-Dec 2017. Atheric™ Pharmaceutical LLC was a biopharmaceutical company focused on the rapid development and commercialization of re-purposed drugs to prevent and treat Zika and other Flavivirus disease. Optimization of high through-put screening techniques for anti-viral drug development.

**Kennesaw State University**
***Adjunct Associate Professor*** 2009-2013

**Beardsworth Consulting Group, Inc**
***Medical Director, Vaccines*** (RW Malone MD, LLC under contract to Beardsworth)
2010-2013
Dr. Malone functioned as the in-house medical vaccine expert for medical monitoring and Scientific Liaison

- Medical liaison to investigator sites including oversight of clinical monitoring
- Provided medical monitoring input including CRF review, 24x7 accessibility to site personnel, assess enrollment waiver requests, SAE review, etc.
- Safety Officer and Medical Representative on project teams
- Medical consultant to clients
- Business development/proposal writing/government contracting

**Solvay Pharmaceuticals, Inc (currently Abbvie)**
***Director, Clinical Development & Medical Affairs, Influenza*** 2006-2008
Led an extended clinical team (both internal and CRO components), providing project and clinical trials management oversight, serving as primary author on clinical protocols, strategic documents including clinical development plans, DSMB/SMC charters, and all clinical documents required to support IND filing. Support and review of outcomes including safety data assessment
Generated and managed cost projections and budgetary oversight, providing strategic management and serving as a communication hub for clinical aspects of a $300 million USD federal contract to develop and license a cell-based influenza vaccine
Solvay's US Government contract for cell-based influenza vaccine was terminated around the end of 2007. At which point the cell-based influenza vaccine project was dissolved.

**Summit Drug Development Services**
***Senior Medical Director*** 2005-2006
Directed due diligence assessments and strategic drug development planning and prepared regulatory submissions and implemented, monitored, and analyzed clinical trials for clients (oncology, vaccines, biologicals, cell/stem cell therapies). Primary author of three pIND, two IND, an Appendix M submission. Served as proposal manager and primary author for a 129M USD federal contract submission focused on pandemic influenza.

**AERAS Global TB Vaccine Foundation**
***Director, Business Development and Program Management*** 2004-2005
Initially serving as consultant, provided leadership primarily focused on tuberculosis vaccine development and proposal development to NGO (B&M Gates), USG (CDC, NIH, DoD).



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**Dynport Vaccine Company, LLC**
***Associate Director, Clinical Research*** 2002-2003

- Served as liaison between product development teams and clinical research support groups.
- Prepared planning documents and product development plans.
- Participated in and supported safety review and assessment of smallpox vaccine product.
- Identified new technologies relevant to product development teams, facilitating integration of same in product development plans.
- Created documents for clinical trials including investigator brochures. Prepared proposal solicitations, technical review of subcontractor proposals. Performed technical review of potential subcontractors, new technologies.
- Assisted business development group in strategic evaluation and planning concerning new business opportunities and managed in-house Publication.

**Intradigm, Corp**
***Co-Founder (one of three co-founders), CSO, Board of Director Member*** 2000-2001
Intradigm was a biotechnology company that develops gene therapeutic technology based on RNA interference. Intradigm merged with Silence Technologies in 2009 and the merged company is now publicly traded. Silence Technologies is involved in developmental research of targeted RNAi therapeutics for the treatment of serious diseases.
Dr. Malone co-founded and helped to secure $2.3 million in V.C. funding, including monies from the Novartis Venture Fund, ETP Venture Capital Fund and the State of Maryland. Performed facilities set-up, infrastructure set-up and Intellectual Property Development. Business and technology development planning, including in-depth business and scientific plan.

**Uniformed Services University of the Health Sciences**
***Dept of Surgery, Clinical Breast Care Program (CBCP) through the Henry M. Jackson Foundation***
***Adjunct Associate Professor***
Chief of Laboratory Science and Director of Tissue Banking 2000-2001

- Worked closely with architect firm to design space, set-up laboratory facilities for the Clinical Breast Care Project, including new facilities design (tissue banking facilities, laboratory, animal rooms, animal surgical suite, office suites) at USUHS and Windber Medical Center, PA
- Hired faculty, technicians, staff for CBCP at both sites, including writing and initiating job descriptions, job interviews, hiring decisions, set-up for re-locations
- Laboratory Supervisor: Tissue banking immunology, cell culture, gene transfer, genetic vaccination research, animal research.

**University of Maryland, Baltimore School of Medicine, Dept. of Pathology**
***Assistant Professor*** 1997-2000
Set-up and ran successful research laboratory in immunology (genetic vaccination) and gene transfer.



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**University of California, Davis Department of Medical Pathology**
1991-1997
***Assistant Professor*** 1993-1997
Director and Founder, Gene Therapy Program (pulmonary, dermal, heart, liver, mucosal and parenteral vaccines).
***Research Fellow, Pathology Resident*** 1991-1993

**Vical, Inc**
***Research Scientist*** 1989

- Set up Vical's molecular biology laboratory.
- Initiated and carried out research in non-viral gene therapy and DNA vaccination.
- Inventor of "naked DNA" gene therapy. (see issued patents for details).
- Inventor of DNA vaccination (see issued patents for details).
- Inventor of "mRNA" gene therapy. Salk institute.
- Inventor of mRNA vaccination. Salk institute.

**LICENSURE / CERTIFICATIONS**
Physician and Surgeon, State of Maryland License 1997-present. #DOO55466

**BOARD OF DIRECTOR POSITIONS:**
Discovery Cure, Inc. Founding Board of Director. 2018-2020
Epivax, Scientific Advisory Board, 2012-2019.

**EDUCATION**

- **HARVARD MEDICAL SCHOOL** *Global Clinical Scholars Research Training Program (fellowship)*
  A year-long comprehensive program that combines on-site (London, Boston) and distance learning, with an average of 15h per week lecture and practicum exercises. 2015-2016. Graduation with distinction (top 5% of graduating class).

- **UNIVERSITY OF CALIFORNIA, DAVIS:** RESEARCH FELLOWSHIP, 1992 – 1993
  *Postgraduate Fellowship Award*

- **UNIVERSITY OF CALIFORNIA, DAVIS MEDICAL CENTER**: 1992
  *Clinical Pathology Internship*

- **NORTHWESTERN UNIVERSITY MEDICAL SCHOOL**: 1991
  ***Doctor of Medicine***

- **UNIVERSITY OF CALIFORNIA, SAN DIEGO**: 1988
  ***Master of Science, Biology***



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- **UNIVERSITY OF CALIFORNIA, DAVIS**: 1984
  ***Bachelor of Science, Biochemistry***

**TEACHING EXPERIENCE**

**Kennesaw State University**
*Associate Professor:*
BTEC 4490 Experimental Design and Analysis (2009): Survey course focused on advanced product development and regulatory aspects of biotechnology and vaccines products.
**University of Maryland, Medical School**
*Assistant Professor:*
Fundamentals of Molecular Biology (Graduate Course, Winter 2000)
Host defenses and Infectious Diseases, small group instructor Year 2 Medical School core curriculum. 1998, 1999
**University of California, Davis**
*Assistant Professor:*
MD 410A/410B. General Systemic Pathology (1992, 1993, 1994, 1995, 1996)
PTX 202. Principles of Pharmacology and Toxicology-Lecturer (1995, 1996)
BCM 214-414. Molecular Medicine-Lecturer (1995, 1996)
IM 295 Cytokines-Lecturer (1996), IDI 280. Molecular Basis of Disease-Lecturer (1996)
**University of California, San Diego**
Biology 111. Cell Biology (Fall 1988). Teaching Assistant under Dr. M. Montal
Biology 123. Embryology laboratory (Spring 1988). Teaching Assistant under Dr. C.Holt
**Santa Barbara City College**
Computer Laboratory (Spring 1981) Teaching Assistant

**PROFESSIONAL OFFICES AND MEMBERSHIPS**

- Harvard Medical School Alumni, 2016- present.
- American Society of Tropical Medicine and Hygiene Member (ASTMH): 2016-2018.
- Virginia Bio: 2016-2018
- IEEE Genomics and Bioinformatics Working Group Member: 2002
- Northern Virginia Technology Council BioMedTech Committee: Co-chair: 2002 – 2003
- Intradigm, Corp. – a new start-up from Novartis, Inc.: Scientific Advisory Board: 2000 – 2001
- Novartis, Inc. (GTI/Systemix & Pharmacokinetics): Scientific Advisory Board and External Portfolio Reviewer: 1999 – 2001
- University of Maryland, Medical School: Pathology Education Policy Committee: 1999 – 2000
- UC Davis:
  - Education Policy Committee Graduate Group in Comparative Pathology: 1996 – 1/1997
  - Member, Biochemistry and Molecular Biology Graduate Group: 1993 – 1/1997
  - Member, Comparative Pathology Graduate Group: 1995 – 1/1997
- Boehringer Mannheim: Scientific Advisory Board: 1992 – 1993



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**EDITORIAL BOARDS**

- Topic Editor, Frontiers in Pharmacology (Respiratory Pharmacology): "Treating COVID-19 with Currently Available Drugs," 2020-present.
- Editor-In-Chief, Journal of Immune Based Therapies and Vaccines. 2009 – 2012, Editor: 2012.
- Gene Therapy/Molecular Biology International Society. 1997 – 2014.
- Reviewer for: Numerous peer-reviewed journals on infectious disease, public health 2016 to present.
- Nucleic Acids Research: 2001 – 2002.
- Molecular Therapy: 1999 – 2001.

**ACADEMIC HONORS**

- Harvard Medical School, Global Clinical Scholar Post Graduate: graduation with distinction (top 5% of graduating class).
- "DNA Vaccine" Recognizes Robert W. Malone, MD, MS, 2013.
- Trainee Investigator Award, American Federation for Clinical Research: 1993.
- Bank of America – Giannini Foundation Medical Research Fellow: 1992 – 1993.
- Henry Christian Award for Excellence in Research, American Federation for Clinical Research: 1992.
- UCDMC Medical Scholars Grant: 1992 – 1993.
- First Place, Northwestern AOA Research Symposium Competition for Medical Students: 1989.
- USPHS Pre-Doctoral Fellowship: 1986 – 1988.
- San Diego Supercomputer Grant for RNA Structure Modeling: 1988.
- Northwestern University MD/ PhD Scholarship: 1984 – 1986.
- Dean's List, UC Davis: 1982 – 1984.
- President's Undergraduate Fellowship Grant for Investigation of Oncogene Expression in Breast Tumor Tissue: 1983 – 1984.
- Edmonson Summer Fellowship, Department of Pathology, UC Davis Medical School: 1984.

**PATENTS ISSUED:**

1. Lipid-mediated polynucleotide administration to deliver a biologically active peptide and to induce a cellular immune response. Assigned to Vical, Inc and licensed to Merck. No. 7,250,404, date of issue: 7/31/07 **Cited in 105 articles.**
2. Lipid-mediated polynucleotide administration to reduce likelihood of subject's becoming infected. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,867,195 B1, date of issue: 3/15/05.
3. Generation of an immune response to a pathogen. Assigned to Vical, Inc and licensed to Merck. US Pat. Ser. No. 6,710,035, date of issue: 3/23/04. **Citations: 37 articles.**
4. Expression of exogenous polynucleotide sequences in a vertebrate, mammal, fish, bird or human Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,673,776, date of issue: 1/6/04.



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5. Methods of delivering a physiologically active polypeptide to a mammal. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6.413.942, date of issue: 7/2/02. **(cited in 150 articles).**
6. Induction of a protective immune response in a mammal by injecting a DNA sequence. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 6,214,804, date of issue: 4/10/01. **Cited in 359 articles.**
7. DNA vaccines for eliciting a mucosal immune response. US Pat. Ser. No. 6,110,898, date of issue: 8/29/00. **Cited in 40 articles.**
8. Formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,925,623 7/20/99.
9. Cationic Transport Reagents. US Pat. Ser. No. 5,892,071 issued 4/06/99.
10. Polyfunctional cationic cytofectins, formulations and methods for generating active cytofectin: polynucleotide transfection complexes. US Pat. Ser. No. 5,824,812 issued 10/20/98.
11. Cationic Transport Reagents. US Pat. Ser. No. 5,744,625 issued 4/28/98.
12. Generation of antibodies through lipid mediated DNA delivery. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,703,055, date of issue: 12/30/97. **Cited in 463 articles.**
13. Induction of a protective immune response in a mammal by injecting a DNA sequence. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,589,466, date of issue: 12/31/96. **Cited in 889 articles.**
14. Delivery of exogenous DNA sequences in a mammal. Assigned to Vical, Inc, licensed to Merck. US Pat. Ser. No. 5,580,859, date of issue: 12/3/96. **Cited in 1234 articles.**
15. Cationic Transport Reagents. US Pat. Ser. No. 5,527,928, date of issue: 6/18/96.

**PUBLICATIONS (selected)**

More Than Just Heartburn: Does Famotidine Effectively Treat Patients with COVID-19? Malone RW. Dig Dis Sci. 2021 Feb 24:1–2. doi: 10.1007/s10620-021-06875-w. Epub ahead of print. PMID: 33625612; PMCID: PMC7903029.

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et al DO.Res Sq. 2020 Jun 22:rs.3.rs-30934. doi: 10.21203/rs.3.rs-30934/v2.
Preprint.PMID: 32702719
Submitted to Frontiers in Pharmacology, ACCEPTED January 30, 2021

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms.
Malone RW, et al DO.Res Sq. 2020 Jun 22:rs.3.rs-30934. doi: 10.21203/rs.3.rs-30934/v2.
Preprint.PMID: 32702719 (cited in 12 articles, downloaded 1200 times).
https://www.researchsquare.com/article/rs-30934/v2

Tomera, Kevin, Malone, Robert and kittah, Joseph, Hospitalized COVID-19 Patients Treated With Celecoxib and High Dose Famotidine Adjuvant Therapy Show Significant Clinical Responses (July 8, 2020).
Available at SSRN: https://ssrn.com/abstract=3646583 or http://dx.doi.org/10.2139/ssrn.3646583



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Submitted to Frontiers in Pharmacology, Accepted with minor revisions/final review, February, 2021.

Ricke, D.O.; Malone, R.W. Medical Countermeasures Analysis of 2019-nCoV and Vaccine Risks for Antibody-Dependent Enhancement (ADE). Preprints 2020, 2020030138 (doi: 10.20944/preprints202003.0138.v1). May, 2020 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3646583

Molecular evolution of Zika virus as it crossed the Pacific to the Americas. Schneider AB, Malone RW, et al. Cladistics. 2017; 12: 10.1111/cla.12178

Zika Virus: Medical Countermeasure Development Challenges. Malone RW, et al. PLoS Negl Trop Dis. 2016;10(3):e0004530. **Cited in 70 articles, viewed over 54,000 times, full PDF downloaded over 11,000 times.**

Zika Fetal Neuropathogenesis: Etiology of a Viral Syndrome. Klase ZA, Khakhina S, Schneider Ade B, Callahan MV, Glasspool-Malone J, Malone R. PLoS Negl Trop Dis. 2016;10(8):e0004877. **Cited in 51 articles, viewed over 13,000 times**.

Antibody mediated epitope mimicry in the pathogenesis of Zika virus related disease. Homan J, Malone RW, et al. BioRxiv. 2016.

Making vaccines "on demand": a potential solution for emerging pathogens and biodefense? De Groot AS, Einck L, Moise L, Chambers M, Ballantyne J, Malone RW Hum Vaccin Immunother. 2013;9(9):1877-84.

Electroporation enhances transfection efficiency in murine cutaneous wounds. Byrnes CK, Malone RW, et al. Wound Repair Regen. 2004;12(4):397-403.

DNA transfection of macaque and murine respiratory tissue is greatly enhanced by use of a nuclease inhibitor. Glasspool-Malone J, …, Malone RW. J Gene Med. 2002;4(3):323-2.

Marked enhancement of macaque respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, …, Malone RW. Gene Med. 2002;4(3):323-2.

Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields. Glasspool-Malone J, Malone RW. In Gene Therapy Methods: Methods Enzymol. 2002;346:72-91

Cutaneous transfection and immune responses to intradermal nucleic acid vaccination are significantly enhanced by in vivo electropermeabilization. Drabick JJ, Glasspool-Malone J, …, Malone RW. Mol Ther. 2001;3(2):249-55. Cited in 192 articles.

Theory and in vivo application of electroporative gene delivery. Somiari S, Glasspool-Malone J, … Malone RW. Mol Ther. 2000;2(3):178-87. Cited in 345 articles.



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Efficient nonviral cutaneous transfection. Glasspool-Malone J, …, Malone RW. Mol Ther. 2000;2(2):140-6. Cited in 138 articles.

Transfer and expression of foreign genes in mammalian cells. Colosimo A, …, Malone RW, et al. Biotechniques. 2000;29(2):314-8, 20-2, 24 passim. Cited in 188 articles.

Specific inhibition of macrophage TNF-alpha expression by in vivo ribozyme treatment. Kisich KO, Malone RW, …, Erickson KL. J Immunol. 1999;163(4):2008-16. Cited in 131 Articles.

Marked enhancement of direct respiratory tissue transfection by aurintricarboxylic acid. Glasspool-Malone J, Malone RW. Hum Gene Ther. 1999;10(10):1703-13

Developing dendritic cell polynucleotide vaccination for prostate cancer immunotherapy. Berlyn KA, …, Malone RW J Biotechnol. 1999;73(2-3):155-79

Models of Cationic Liposome Mediated Transfection. Gene Therapy and Molecular Biology. Ahearn A, Malone RW. Vol 4. Gene Therapy and Molecular Biology 1999;4

Mucosal immune responses associated with polynucleotide vaccination. Malone JG, …, Malone RW. Behring Inst Mitt. 1997(98):63-72

Delivery of exogenous DNA sequences in a mammal. P Felgner, …, R Malone, D Carson. Biotechnology Advances. 1997 15 (3-4), 763-763

Cationic lipid-mediated gene delivery to murine lung: correlation of lipid hydration with in vivo transfection activity. Bennett MJ, …, Malone RW, Nantz MH. J Med Chem. 1997;40(25):4069-78

Improved method for the removal of endotoxin from DNA. Montbriand PM, Malone RW. J Biotechnol. 1996;44(1-3):43-6. Cited in: 43 articles

Toxicity of cationic lipid-ribozyme complexes in human prostate tumor cells can mimic ribozyme activity.Freedland SJ, Malone RW, et al. Biochem Mol Med. 1996;59(2):144-53

Considerations for the design of improved cationic amphiphile-based transfection reagents. Bennett MJ, …, Malone RW. Journal of Liposome Research 1996;6(3):545-65

Structural and functional analysis of cationic transfection lipids: the hydrophobic domain. Balasubramaniam RP, …, Malone RW. Gene Ther. 1996;3(2):163-72. cited in 172 articles.

The counterion influence on cationic lipid-mediated transfection of plasmid DNA.Aberle AM, Bennett MJ, Malone RW, Nantz MH. Biochim Biophys Acta. 1996;1299(3):281-3

Direct gene tranfer into mouse muscle in vivo. N Shafee, ..., RW Malone, et al. International Journal of Virology 2 (1), 33-38



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A flexible approach to synthetic lipid ammonium salts for polynucleotide transfection. MJ Bennett, RW Malone, MH Nantz. Tetrahedron letters 36 (13), 2207-2210

Tfx-50 Reagent, a new transfection reagent for eukaryotic cells. Schenborn E, …, Malone RW, et al. 1995

Hepatic gene expression after direct DNA injection. Hickman MA, Malone RW, et al. Advanced Drug Delivery Reviews. 1995;17(3):265-71

Cholesterol enhances cationic liposome-mediated DNA transfection of human respiratory epithelial cells. Bennett MJ, …, Malone RW. Biosci Rep. 1995;15(1):47-53

Dexamethasone enhancement of gene expression after direct hepatic DNA injection. Malone RW, et al. J Biol Chem. 1994;269(47):29903-7

Gene expression following direct injection of DNA into liver. Hickman MA, Malone RW, et al. Hum Gene Ther. 1994;5(12):1477-83. Cited in 306 articles.

Cationic liposome-mediated RNA transfection. Dwarki VJ, Malone RW, Verma IM. Methods Enzymol. 1993;217:644-54. Cited in: 88 articles.

Successful gene transfection fo respiratory epithelium invitro using polyamine containing cationic lipids. CB Robinson, RW Malone, J Jessee, G Gebeyehu, R Wu AMERICAN REVIEW OF RESPIRATORY DISEASE 147 (4), A546-A546

Direct gene transfer into mouse muscle in vivo. Wolff JA, Malone RW, et al. Science. 1990;247(4949 Pt 1):1465-8. **Cited in 4,695 articles.**

Cationic liposome-mediated RNA transfection. Malone RW, Felgner PL, Verma IM. Proc Natl Acad Sci U S A. 1989;86(16):6077-81. **Cited in 717 articles.**

mRNA Transfection of cultured eukaryotic cells and embryos using cationic liposomes. Malone RW. Focus. 1989;11:61-8

High levels of messenger RNA expression following cationic liposome mediated transfection tissue culture cells. Malone R, Kumar R, Felgner P. NIH Conference: "Self-Cleaving RNA as an Anti-HIV Agent" (Abstract). Washington, DC June 1989.

A novel approach to study packaging of retroviral RNA by RNA transfection (Abstract). RW Malone, P. Felgner, I. Verma. RNA Tumor Viruses, May 17-18, 1988. Cold Spring Harbor

Mammary tumors in feral mice lacking MuMTV DNA. Gardner MB, Malone RW, …, Cardiff RD, et al. J Exp Pathol. 1985;2(2):93-8



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Hyperplastic and neoplastic changes in the mammary glands of feral mice free of endogenous mouse mammary tumor virus provirus. Faulkin LJ, …, Malone RW, et al. J Natl Cancer Inst. 1984;73(4):971-82.

**PUBLISHED ABSTRACTS: Over 50 published**

**CHAIRPERSON/ORAL PRESENTATIONS BY INVITATION**: **Over 40 Invitations**
(Only the most recent events listed)

- Vaccines R&D, 2019. Keynote Speaker, Panel Moderator: Boston, MA. 18-20 November, 2019.
- Repurposing drugs for Infectious Disease Outbreaks. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017 (Chairperson)
- Accelerated Discovery and Development of re-purposed licensed drugs for Zika virus outbreak antiviral prophylaxis and therapy. International Conference on Zika Virus. Washington, DC Feb 22-25, 2017. (Oral Presentation)
- Zika Virus: Accelerating Development of Medical Countermeasures by Re-purposing Licensed Drugs. Bridging the Sciences: Zika Virus. Emery, Atlanta, GA 1-3 May, 2016. (Oral Presentation)
- Speaker/Round table- Zika virus: Challenges for Medical Countermeasure Development. World Vaccine Conference. Washington, DC. 29-31 March, 2016.
- The World Health Organization (WHO) Consultation for Zika Virus: Research and Development. Presentation of Drug Development TPP. Geneva, Switzerland. 12-14 March, 2016. (Oral Presentation)
- Keynote Speaker: Ebola Vaccine in 12 months, Global Village, and the Need for Speed. Vaccines R&D, Baltimore, MD. 2-4 November, 2015. (Keynote Speaker)
- Current USG contracting Opportunities and Initiatives from the point of View of Vaccine Developers. World Vaccine Conference, Washington, DC. 24-26 March, 2014. (Oral Presentation)
- World Vaccine Conference, Washington, DC. 24-26 March, 2014 Preclinical and Clinical Vaccine Research. (Session Chair)
- PHEMCE Modeling Workshop "Operational Decision Making using Innovative Modeling, Analysis, and Visualization Tools", Sponsored by Deloitte. 2013 (Conference Co-Organizer and Coordinator/Oral Presentation)



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- "Vaccine Production Strategies: Ensuring Alignment and Sustainability" The World Health Organization (WHO) Global Action Plan for Influenza Vaccines. Geneva, Switzerland. 12-14 July 2011 (Oral Presentation)

**RECENT STUDY SECTIONS (selected):**

- Chairperson, NIH/NIAID/DMID Special Emphasis Panel, Development of Vaccines to Combat Antibiotic Resistant Bacteria September 2019.
- Chairperson, NIH/NIAID Special Emphasis Panel, December 2018.
- Reviewer, NIH/NIAID Special Emphasis Panel, December 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, for "Congressionally Directed Medical Research Programs (DMRDP), 2012.
- Committee member and reviewer for NIH/NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines. 2011
- Chair and reviewer for NIH/NIAID: Partnerships in Biodefense Immunotherapeutics. 2011
- NIH/NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel. 2010
- Chairperson and scientific reviewer for NIH/NIAID Omnibus BAA 2017-1: Research Area 5 (N01) ZAI1-KP- M-C6 (Topic 5: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases), September 2017.
- Scientific reviewer for NIH/NIAID Special Emphasis Panel/Scientific Review Group 2017/08 ZRG1 IMM-R (12) B (Non-HIV Microbial vaccines), June 2017.
- Chairperson and scientific reviewer for Department of Defense, U.S. Army Medical Research and Materiel Command, "CDMRP: Defense Medical Research & Development Program (DMRDP), 2012.
- Chairperson and scientific reviewer for NIH/NIAID Committee on Partnerships in Biodefense Immunotherapeutics, Fall 2011.
- Committee member and reviewer for NIH/ NIAID Committee for Development of Technologies that Accelerate the Immune Response to BioDefense Vaccines, Fall 2011.
- NIH/ NIAID Committee member and reviewer for Development of Technologies to Facilitate the Use of, and Response to Biodefense Vaccines," Special Emphasis panel, 2010.
- NIH Study Section K01 Breast Cancer Study Section: July 1997
- NIDDK Special Emphasis Panel Review Committee for Competing Continuation Program Project: April 1999 and April 1998
- NIAID Study Section "Innovative Grant Program for Approaches in HIV Vaccine Research": 1998

**BOOKS AND BOOK CHAPTERS**



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- Malone RW. *"Present and Future Status of Gene Therapy.' Intro Chapter in Advanced Gene Delivery: From Concepts to Pharmaceutical Products*." Editor: Allain Rolland. Harwood Academic Pub. 1998, republished 2014.

- *Enhancing direct in vivo transfection with nuclease inhibitors and pulsed electrical fields*. Glasspool-Malone J, Malone RW. In *Gene Therapy Methods: Methods Enzymol.* 2002;346:72-91

- Malone RW. *"Toxicology of non-viral gene transfer"*. Editor, Walsh B. In*: "Non-Viral Therapeutics: Advances, Challenges and Applications for Self-Assembling Systems*." IBC's Biomedical Library Series. (1996) 4.1



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**CERTIFICATE OF SERVICE**

I hereby certify that on October 14, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States District Court Western District of Washington by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

I further certify that some of the participants in the case are not CM/ECF users. I have I served a copy of the foregoing upon all counsel of record via email as agreed.

| | |
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DATED this 14th day of October 2021.

/s/ Nathan J. Arnold
Nathan J. Arnold, WSBA No. 45356



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